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In the Supreme Court of the United States

OCTOBER TERM, 1956

No. 271

IN THE MATTER OF RUTHERFORD T. CARLISLE, AN INDIVIDUAL TRADING AS CARLISLE DRUGS, PETITIONER

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

OPINION BELOW

The opinion of the Court of Appeals (Pet. App. V, 2-8)[1] is not yet reported.

JURISDICTION

The judgment of the Court of Appeals was entered on May 31, 1956 (Pet. App. IV, 1). A petition for rehearing was denied on June 30, 1956. The petition

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[1] Petitioner included appendices I, II and III in his original petition and continued the consecutive numbering therein. Appendices IV and V, the judgment and opinion of the Court of Appeals, were bound separately and the pagination commences with the number 1.

for a writ of certiorari was filed on July 23, 1956. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

QUESTIONS PRESENTED

1. Whether the court of appeals had jurisdiction to entertain an appeal from an order of the district court dismissing certain counts of a criminal information when it was not clear whether the order of the district court (which that court refused to clarify) was based on a construction of the statutes involved or upon the sufficiency of the pleadings.

2. Whether the dismissed counts of the information were duplicitous.

3. Whether the information was defective for failure to state that the original package contained the language, "Warning—may be habit forming," the omission of which statement constitutes misbranding under 21 U.S.C. 352(d), when petitioner was not charged with misbranding under § 352(d) but rather with refilling a prescription without authorization, another type of of misbranding under § 353(b)(1).

4. Whether the statutory definition of "misbranding" in 21 U.S.C. 353(b)(1), when construed with 21 U.S.C. 331(k), which denounces misbranding, and 21 U.S.C. 333, which fixes the penalty for that offense, is sufficiently definite for judicial enforcement.

STATUTES INVOLVED

The Criminal Appeals Act, 18 U.S.C. 3731, provides in pertinent part:

> An appeal may be taken by and on behalf of the United States from the district courts direct to the Supreme Court of the United States in all criminal cases in the following instances:

From a decision or judgment setting aside, or dismissing any indictment or information, or any count thereof, where such decision or judgment is based upon the validity or construction of the statute upon which the indictment or information is founded.

* * * * *

An appeal may be taken by and on behalf of the United States from the district courts to a court of appeals in all criminal cases, in the following instances:

From a decision or judgment setting aside, or dismissing any indictment or information, or any count thereof except where a direct appeal to the Supreme Court of the United States is provided by this section.

The Federal Pure Food, Drug and Cosmetic Act of June 25, 1938, 52 Stat. 1040, as amended, 21 U.S.C. 301 *et seq.*, provides in pertinent part:

Section 331. *Prohibited acts.*

The following acts and the causing thereof are prohibited:

* * * * *

(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for

sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

* * * * *

Section 333. *Penalties.*

(a) *Violation of Section 331.*

Any person who violates any of the provisions of section 331 of this title shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than $1,000, or both such imprisonment and fine; * * *

Section 352. *Misbranded drugs and devices.*

A drug or device shall be deemed to be misbranded—

* * * * *

(d) *Habit-forming substances.*

If it is for use by man and contains any quantity of the narcotic or hypnotic substance alpha eucaine, barbituric acid, betaeucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marihuana, morphine, opium, paraldehyde, peyote, or sulphonmethane; or any chemical derivative of such substance, which derivative has been by the Administrator, after investigation, found to be, and by regulations designated as, habit forming; unless its label bears the name and quan-

tity or proportion of such substance or derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

* * * * *

Section 353(b). *Prescription by physician: exemption from labeling and prescription requirements; misbranded drugs; compliance with narcotic and marihuana laws.*

(1) A drug intended for use by man which—

(A) is a habit-forming drug to which section 352(d) of this title applies;

* * * * *

shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug; or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

STATEMENT

On January 6, 1954, the Government filed, in the United States District Court for the Southern District of Florida, a six-count criminal information against petitioner, charging violations of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 301 *et seq.* (R. 1-7).

Counts I-III of the information charged petitioner with dispensing dextro-amphetamine and thyroid tablets without a prescription.

Counts IV, V and VI charged petitioner with misbranding drugs in violation of 21 U.S.C. 331(k). Each of the last three counts charged that petitioner, on different occasions, caused a quantity of certain drugs, held for sale after shipment in interstate commerce, to be dispensed as a refill of a prescription without the authorization of the prescribing physician, which resulted in the drug's being misbranded under 21 U.S.C. 353(b)(1) (R. 4-7). The drugs involved were alleged to be within the class of drugs described in 21 U.S.C. 353(b)(1)(a), *i.e.*, "* * * a habit-forming drug to which 21 U.S.C. 352 (d) * * * applies * * *."

Petitioner moved to dismiss the information, citing thirteen grounds therefor, including alleged defects in the information and attacks on the validity of the statute (Pet. 6-7; R. 7-10). The district court granted the motion to dismiss Counts IV-VI, stating (R. 33):

> * * * Counts IV, V and VI are dismissed on authority of Judge Barker's dismissal of similar counts by orders entered August 1, 1952, in the following cases: *United States* v. *Kilgore*, 6016-T-Cr; *United States* v. *Pomeroy*, 6017-T-Cr; and *United States* v. *Webb's City Incorporated*, 6018-T-Cr * * *.

The prior orders mentioned by the district court had been entered on informations filed in 1950, before the amendment of the Food and Drug Act, effective April 26, 1952, specifically made the unauthorized refilling of a prescription for a habit-forming drug an act of

misbranding (21 U.S.C. 353(b)(1), *supra*, p. 5).[2] The charge in those cases was that the unauthorized refilling resulted in the drug's being misbranded for failure to carry the warning that it might be habit forming (in violation of 21 U.S.C. 352(d)) and failure to bear adequate directions for use (in violation of 21 U.S.C. 352(f)(1)). Since a drug dispensed on prescription was exempt from these labeling requirements (21 U.S.C. (1946 ed.) 353(b)), Judge Barker, in those cases, held in substance that, before the 1952 amendments, the refilling was also exempt. Judge Barker referred to the amendment involved in the instant case, 21 U.S.C. 353(b) as a "clarifying and definitive" amendment (Pet. App. I-III, 28-33).

On the basis of the difference between the instant case and the cases decided by Judge Barker, the government moved for a rehearing, seeking reinstatement of the dismissed counts or a clarification of the basis for dismissal (R. 34-36). The motion was denied (R. 37). The government then appealed to the Court of Appeals for the Fifth Circuit which upheld both the sufficiency of the indictment as a pleading and the constitutionality of the statute (Pet. App. V, 3-8).

ARGUMENT

1. Petitioner contends that the district court's dismissal of Counts IV to VI was predicated solely upon the unconstitutionality of the statute on which those counts were founded, with the result that the appeal

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[2] Count I of the Kilgore information is printed as an appendix to this brief. Counts II-VIII charge violations of statutory sections identical to those alleged to have been violated in Count I. The other two informations, both of which are very lengthy, are the same as the Kilgore information, except as to such matters as dates and names.

by the government lay only to this Court under 18 U.S.C. 3731 (Pet. 9-12). In view of the different situation involved in the instant case from that presented by the orders of Judge Barker to which the district court referred (see the Statement, *supra*, p. 6), and the refusal of the district court to clarify its decision, it was impossible for the government to determine the basis of the court's action. There is not a word in the district court's decision, nor was there any in Judge Barker's prior decision, as to unconstitutionality. And since the district court in this case had before it a statute which was not in effect at the time of Judge Barker's decision, on which the court purported to rely, it was impossible to tell whether the district court was construing the new statute or the sufficiency of the information. Petitioner's motion to dismiss (R. 7-9) had concentrated more on alleged insufficiency of the pleading than on the invalidity of the pertinent sections of the Food and Drug Act. Even in his petition for certiorari, petitioner argues that the information is duplicitous (Pet. 12, 13), as well as vague and indefinite (Pet. 15, 22-23), while simultaneously asserting that the only real issue in this case is one of statutory construction.[3] The government's motions for an order clarifying the basis for dismissal and for a rehearing (R. 34-36) fully apprised the district court of its error in predicating its dismissal on Judge Barker's prior decision, which antedated the amendment of the statute. The

[3] We note parenthetically that § 353(b)(1) has been incorrectly paraphrased by petitioner, undoubtedly as a result of a typographical error (Pet. 13). The petition states that the section provides that none of the drugs "can be dispensed upon written prescription." If the word "except" is inserted between the words "dispensed" and "upon," the correct meaning of the statute is conveyed.

court's refusal to grant these motions (R. 37) tended to indicate that the order would stand because of the alleged defects in the pleading. Under the circumstances, the district court's order appeared to involve a construction of the information, apart from whether it also involved a construction of the statute.[4]

If defects of criminal pleading as well as questions of statutory construction form the basis of the district court's decision, this Court cannot entertain a direct appeal. *United States* v. *Jones*, 345 U.S. 377, 378; *United States* v. *Wayne Pump Co.*, 317 U.S. 200, 203, 208; *United States* v. *Borden Co.*, 308 U.S. 188, 193. Hence, the appeal was properly taken to the court of appeals, which then had authority to pass upon the construction of the pleading and of the statute. *United States* v. *Swift & Co.*, 318 U.S. 442, 444; *United States* v. *Johnston*, 227 F. 2d 745, 749 (C.A. 3); *United States* v. *Pepper Bros.*, 142 F. 2d 340, 342 (C.A. 3).

2. Petitioner contended in the lower courts, as he does here, that the information is duplicitous (Pet. 12-13, 23-24), in that he is charged with dispensing a drug without a prescription in violation of 21 U.S.C. 353(b)(1) and with misbranding in violation of 21 U.S.C. 331(k). As pointed out by the court of appeals, this position has no merit (Pet. App. V, 7). Section 353(b)(1) defines unauthorized refilling of prescrip-

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[4] Petitioner cites *Taylor* v. *United States*, 207 U.S. 120, 126, for the proposition that there is a presumption the judgment was based on the construction of the statute (Pet. 18). This Court did not so hold. Properly punctuated, the portion of the opinion quoted by petitioner is as follows:

"The United States brings a writ of error under the Act of March 2, 1907 * * * on the ground, it must be presumed, that the judgment was based upon the construction of a statute."

The commas after "ground" and "presumed" are omitted in the petition.

tions for habit-forming drugs as misbranding.[5] Section 333 provides the penalty for misbranding. The statutes together denounce one crime, misbranding, and that was the only crime charged in the information. See *United States* v. *2600 State Drugs, Inc.*, (C.A. 7), No. 11654, decided July 11, 1956, pending on petition for certiorari, No. 309, this Term, dealing with the same issues and citing the opinion of the court of appeals in the instant case.

The reference to § 352(d) in § 353(b)(1)(A) serves merely to identify the habit-forming drugs which cannot be dispensed without a prescription. As was said in *United States* v. *Arnold's Pharmacy, Inc.*, 116 F. Supp. 310, 312 (D. N.J.):

> * * * The * * * charge in this case is the sale of a "habit-forming drug to which Section 352(d) of this Title applies," contrary to Section 353(b)(1)(A), in that it was to be dispensed only upon a written prescription of a physician, but in fact was dispensed without any such authorization; that accordingly same was a statutory "misbranding," misbrandings being a violation of the Act under Section 331(k), the penalties for such misbrandings being set forth in Section 333(a). When read with care, such statutory provisions appear neither vague nor contradictory, the allusion to Section

[5] The habit forming drugs to which § 353(b)(1) relates are defined in Section 352(d) to include barbituric acid or any chemical derivative thereof designated by the Secretary of Health, Education and Welfare, after investigation, as habit forming. The specific drugs mentioned in the information were designated as derivatives of barbituric acids. 21 C.F.R. (1949 ed.) 145.1. The regulations have the force of law. *Federal Crop Insurance Corp.* v. *Merrill*, 332 U.S. 380; *Archambault* v. *United States*, 224 F. 2d 925, 928 (C.A. 10).

352(d) being merely descriptive of the character of the drug, and not constituting a separate offense from that set forth above.

3. Petitioner's assertion that the court of appeals erred in failing to consider that the information did not allege that the original stamped package contained the language, "Warning—may be habit forming" (Pet. 22-23), is frivolous. Petitioner was *not* charged with misbranding by failing to label correctly under 21 U.S.C. 352(d) but rather with misbranding by refilling a prescription without authorization under 21 U.S.C. 353(b)(1). The 1952 amendment of Section 353(b) specifically prohibits the unauthorized refilling of a prescription for a habit forming drug, regardless of the validity of the original dispensing.

4. Petitioner attacks the constitutionality of § 353 (b)(1) and 331(k) because these sections purport to affix a meaning to the word "misbranded" which departs from the definition of the word in *Webster's Dictionary*, thus, he argues, rendering the statute void for vagueness and indefinite (Pet. 13-18).

As pointed out by the court of appeals in the instant case, Congress, in passing the 1952 amendment, established by law that the act of refilling a prescription without authorization of the issuing physician is misbranding (Pet. App. V, 7). This established, there is required only resort to § 331(k), which denounces the offense of misbranding, and § 333, which fixes the penalty for that offense. Congress, if it chooses, may adopt a special definition for particular words so long as the meaning of the statute is clear. *Walling* v. *Portland Terminal Co.*, 330 U.S. 148, 150-151; *Western Union Telegraph Co.* v. *Lenroot*, 323 U.S. 490, 502. The exact

contention made by petitioner here, that in ascertaining the meaning of "misbranded" no consideration may be given to the statutory definition, was rejected by the district court in *United States* v. *Gibson*, 135 F. Supp. 807, 808 (E.D. Pa.):

> * * * The two sections [21 U.S.C. 333, 353(b)(1)] must be read together to ascertain the meaning of "misbranded" as used in the Act. It is provided that the prohibited act of dispensing such drug without prescription "shall be deemed to be an act which results in the drug being misbranded while held for sale" [§ 353(b)(1)].

Here, the particular act which Congress has prohibited is clearly and definitely set forth. The statute is therefore sufficiently definite to "give notice of the required conduct to one who would avoid its penalties, and to guide the judge in its application and the lawyer in defending one charged with its violation." See *Boyce Motors Lines* v. *United States*, 342 U.S. 337, 340; *Jordan* v. *DeGeorge*, 341 U.S. 223, 231-232.[6]

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[6] In *United States* v. *Cardiff*, 344 U.S. 174, cited by petitioner (Pet. 14-15), the statute made federal factory inspection dependent upon consent of the factory operator and then made refusal to give consent a crime. What would be a valid or invalid refusal was not defined or limited. Here, the act made a crime is narrow, specific and definite.

CONCLUSION

For the reasons stated, it is respectfully submitted that the petition for a writ of certiorari should be denied.

J. Lee Rankin,
Solicitor General.
Warren Olney III,
Assistant Attorney General.
Beatrice Rosenberg,
Albert M. Christopher,
Attorneys.

August 1956.

APPENDIX

IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF FLORIDA

UNITED STATES OF AMERICA

v.

WELLS B. KILGORE, an individual, trading as Kilgore's Pharmacy, and Weldon R. Rehburg, an individual

No. 6016-T-Criminal

(21 U.S.C. 331 and 333)

COUNT 1

The United States Attorney charges:

That within the period from on or about June 23, 1950 to on or about September 30, 1950, Eli Lilly and Company shipped from Indianapolis, Indiana into the State of Florida, a bottle of Seconal Sodium capsules, a drug, which bottle was labeled, marked and branded, in part, as follows:

> CAUTION—To be dispensed only by or on the prescription of a physician.

That thereafter, on or about October 24, 1950 and while a number of capsules of said drug were being held for sale after shipment in interstate commerce, as aforesaid, at the Kilgore's Pharmacy, St. Petersburg, Florida, Wells B. Kilgore, an individual trading and doing business as Kilgore's Pharmacy, the defendant herein, did, at St. Petersburg, Florida, within the Southern District of Florida, cause a number of capsules of said drug to be repacked and dispensed to one William Stokes, in a vial labeled and marked in part "No. 41935 Dr. Wood One capsule at bedtime as needed

for sleep," without a physician's prescription therefor;

That said acts of causing the repacking and dispensing resulted in said drug in said vial being misbranded within the meaning of Title 21, United States Code, in that said drug failed to bear a label containing an accurate statement of the quantity of contents (21 U.S.C. 352(b)(2)); in that said drug was for use by man and contained seconal sodium, a chemical derivative of barbituric acid, which derivative had been by the Federal Security Administrator, after investigation, found to be and by regulation (21 CFR, 1949 Ed., 145.1) designated as habit forming, and the label of said drug in said vial failed to bear the name and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming" (21 U.S.C. 352(d)); and in that the labeling of said drug failed to bear adequate directions for use (21 U.S.C. 352(f)(1));

That said acts were acts caused to be done by the said defendant while said drug was being held for sale after shipment in interstate commerce, which resulted in said drug in said vial being misbranded as aforesaid, in violation of Title 21, United Code, Section 331 (k).

* * * * *

———— ——,
United States Attorney,
For the Southern District of Florida.

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